SpineWorks Anterior Lumbar Device Instructions for Use

Single Use only

DESCRIPTION

The SpineWorks anterior lumbar intervertebral body fusion devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. They are designed to be used in conjunction with supplemental spinal fixation instrumentation. The series is comprised of cages of various fixed heights and shapes for placement in the cervical or lumbar spine. There are different cages designed for specific regions of the spine and approaches to the spine. Each cage has a hollow center to allow placement of graft material inside of the cage. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion.

The SpineWorks anterior lumbar intervertebral body fusion devices are made from the VERTEPEEK radiolucent material with embedded tantalum x-ray markers as specified in ASTM F2026 and ASTM F560, respectively.

INDICATIONS

PRECAUTIONS

Intervertebral body fusion should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Surgical technique manuals are available for detailed instructions on the correct use of the SpineWorks anterior lumbar fusion device. The contents of these manuals alone are not adequate for complete instruction in the use of this system. Even for surgeons already experienced in spinal instrumentation and intervertebral body fusion procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

CONTRAINDICATIONS

- spondylolisthesis higher than grade I (not for the use with a pedicle screw fixation system)
- reduced bone density, which does not guarantee a sufficient resting stability (e. g. osteoporosis)
- fractures
- tumours
- scoliosis
- Active infection
- Allergy to titanium, titanium alloy or PEEK
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Suspected or documented allergy or intolerance to composite materials
- Any case not needing a fusion
- Any case not described in the indications
- Any patient unwilling to cooperate with postoperative instructions
- Patients with a know hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
- Spondylolisthesis unable to be reduce to Grade 1
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case that requires the mixing of metals from two different components or systems
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level to be treated

POSSIBLE ADVERSE EFFECTS

Note: A further surgery might become necessary to correct adverse effects.

This list may not include all complications caused by the surgical procedure itself.

1. Bending or fracture of implant. Loosening of the implant.
2. Implant material sensitivity, or allergic reaction to a foreign body.
3. Infection, early or late.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensations due to the presence of the device.
6. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
7. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
8. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
9. Bursitis.
10. Paralysis.
11. Death.
12. Spinal cord impingement or damage.
13. Fracture of bony structures.
14. Reflex sympathetic dystrophy.
15. If a pseudarthrodesis occurs coupled with the SpineWorks anterior lumbar fusion device, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
16. Degenerative changes or instability in segments adjacent to fused vertebral levels.

Warning: An entirely satisfactory result is not always achieved in every surgical case. This particularly applies to spinal surgery, in which numerous external factors may compromise the results.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

The risk of device expulsion and migration is higher without the use of supplemental fixation.

The use of dissimilar materials (e.g., titanium and stainless steel) should not be used together because of the risk of galvanic corrosion.

The SpineWorks anterior lumbar intervertebral body fusion devices have not been evaluated for safety and compatibility in the MR environment. The SpineWorks anterior lumbar intervertebral body fusion devices have not been tested for heating or migration in the MR environment.

STERILIZATION

Implants and instruments of the SpineWorks anterior lumbar intervertebral body fusion devices are supplied clean and NOT STERILE. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated steam sterilizer effective sterilization may be achieved using the following parameters:

Method:	Steam
Cycle:	Prevacuum
Temperature:	132ºC/270ºF
Exposure time:	4 min

CAUTION

Federal Law restricts this device to sale by or on the order of a Physician.

Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

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